









PMCF Report, 15th November 2022

#DX6LM



Equine-derived cancellous granules

Natural bone substitutes of equine origin developed and produced by Tiss'You through its own patented process EstRem (WO2020058813A1).



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Absorbable collagen membrane

Made from highly pure type I atelocollagen of equine origin, produced by Tiss'You.



Post-extraction sockets

Guided Bone Regeneration



33 patients

29-80 years



Bone defects

Surgical cleaning, bone filling, and membrane application



Up to 6 months of follow-up



Probing depths and X-rays

outcomes

Background

Regenerative therapy in dentistry involves the replacement and/or regeneration of oral tissues altered as a result of disease or injury. Furthermore, traumatic extraction has also been associated with additional loss of bone. In the healing phase after extraction, alveolar bone undergoes additional atrophy as a result of the natural remodelling process. This begins immediately after extraction and may result in up to 50% resorption of the alveolar ridge with impact on dental implant placement.

Post-extractive socket preservation procedures aim to prevent alveolar ridge atrophy and maintain adequate dimensions of bone in order to facilitate implant placement. Here we report the clinical results of a guided bone regeneneration strategy tackled with a natural bone substitutes of equine origin developed and produced by Tiss'You through its own patented process EstRem, and an absorbable collagen membrane produced by Tiss'You.

Methods

In this prospective study, we aimed to comprehensively address the treatment outcomes for post-extractive sockets in 33 patients. The chosen intervention encompassed a multi-faceted approach involving meticulous surgical cleaning, augmentation with heterologous bone substitutes (Tiss'You), and the utilization of an absorbable collagen membrane (Tiss'You). The membrane was securely affixed using a criss-cross suture technique applied to the mucosal flaps.

Primary objective was to assess bone remodeling by measuring probing depths at various distances (central, medial, distal, lingual/palatine, and vestibular) at baseline, 3 months, and 6 months. X-ray images were also obtained at these time points to further understand changes in bone density and structure.

Results

No adverse effects were observed. Mean post-operative pain after treatment at 15 days was 2.8 \pm 0.7. None of the patients reported pain at 3 and 6 months.

Optimal bone regeneration was observed in all treated patients through probing depths.

Radiographs showed appropriate bone level (Fig. 1); measurements revealed minimal resorption of 0.14 mm (average among the 5 probed sites) at 6 mon-

ths, with maintenance of initial bone volume (Table 1)

Xenys Apatite acted as a scaffold to allow osteoblastic cells for the formation of a new native bone structure and contributes to the long-term maintenance of alveolar volume.

A complete restitutio ad integrum can be observed 6 months after surgery.







Figure 1. Representative x-ray images of treated defect at (**A**) 3 and (**B**) 6 months showing successful bone regeneration. Representative image showing (**C**) soft tissue healing at 3 months.

3 months	6 months	
5.0	5.1	Central
6.9	6.7	Medial
6.0	5.9	Distal
6.4	6.2	Lingual/Palatine
6.4	6.5	Vestibular

Table 1. Mean distances in probing sites (mm).



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HETEROLOGOUS BONE MATRIX
PRODUCED BY TISS'YOU

